

JUN 27 2003

K031521

PART IX. 510(k) SUMMARY

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

510(k) SUMMARY FOR AOSEPT Clear Care Cleaning and Disinfecting Solution

1. Submitter Information

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person: Steven Dowdley
Telephone No. 678-415-3897

2. Device Name

Classification Name: Soft (hydrophilic) Contact Lens Solution
Proprietary Name: AOSEPT Clear Care Cleaning and Disinfecting Solution

3. Predicate Device(s)

AOSEPT Clear Care Cleaning and Disinfecting Solution

4. Description of the Device

The AOSEPT Clear Care Cleaning and Disinfecting Solution is an aqueous solution contains hydrogen peroxide 3% (stabilized with phosphonic acid), sodium chloride, a phosphate buffer system and a non-ionic surfactant. The solution is indicated for use in simultaneous cleaning and disinfecting, daily protein removal, and storing of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

5. Indications for Use

AOSept Clear Care Cleaning and Disinfecting Solution is indicated for use in simultaneous cleaning, daily protein removal, disinfecting, and storing of soft (hydrophilic) contact lenses (including silicone hydrogel lenses) as recommended by your eye care practitioner.

6. Description of Safety and Substantial Equivalence

A series of preclinical and clinical studies have been completed on this product and were previously submitted under submission K003345 and K013512. The non-clinical and clinical studies were completed to demonstrate the substantial equivalence of AOSEPT Clear Care Cleaning and Disinfecting Solution to other currently marketed solutions. All testing was conducted in accordance with and in conformance to applicable device regulations. Results demonstrate the solution is non-toxic and biocompatible, and is comparable to other currently marketed soft contact lens solutions.

Silicone Hydrogel Lens Compatibility Data

A study was conducted to verify that Lotrafilcon A (silicone hydrogel) lenses are compatible with AOSEPT Clear Care Cleaning and Disinfecting Solution. The study showed there was no significant difference between AOSEPT Clear Care Cleaning and

Disinfecting Solution and the saline control solution, with respect to optical and physical changes in the measured properties of the lenses. AOSEPT Clear Care Cleaning and Disinfecting Solution meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry, Premarket Notification 510(k) Guidance Document for Contact Lens Care products.

In Vitro Cleaning Efficacy

Results of the study showed that AOSEPT Clear Care is substantially equivalent to SOLO-Care Multipurpose Solution in terms of daily protein removal. This data was previously submitted and reviewed in original 510(k) submission - K003345..

Cytotoxicity

A series of cytotoxicity studies were previously conducted to demonstrate the safety of AOSEPT Clear Care. Results of the testing demonstrated that AOSEPT Clear Care is non-cytotoxic and is a non-irritant. This data was previously submitted and reviewed in original 510(k) submission - K003345.

Microbiology

A series of microbiology studies were previously completed to demonstrate the microbiological efficacy of AOSEPT Clear Care. These studies were previously submitted under 510(k) K003345. These studies demonstrate that AOSEPT Clear Care meets the stand-alone criteria of the disinfection efficacy test of the FDA May 1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

Clinical Testing

A series of clinical studies have been conducted, submitted and reviewed in 510(k) submissions K003345 and K013512. Data from the clinical studies supported the substantial equivalence of AOSEPT Clear Care.

7. Substantial Equivalence

The data provided in this 510(k) submission concludes that AOSEPT Clear Care Cleaning and Disinfecting Solution is substantially equivalent to AOSEPT Clear Care Cleaning and Disinfecting Solution for cleaning, rinsing, chemical (not heat) disinfecting, protein removal, and storing soft (hydrophilic) contact lenses (including silicone hydrogel lenses) as recommended by your eye care practitioner.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2003

CIBAVision Corporation
c/o Steven Dowdley, RAC
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, GA 30097

Re: K031521

Trade/Device Name: AOSEPT Clear Care Cleaning and Disinfecting Solution

Regulation Number: 21 CFR 886.5928

Regulation Name: Soft (hydrophilic) contact lens care products

Regulatory Class: Class II

Product Code: LPN

Dated: May 12, 2003

Received: May 28, 2003

Dear Mr. Dowdley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number: (Number to be assigned)

Device Name: AOSept Clear Care Cleaning and Disinfecting Solution

Indications for Use:

AOSept Clear Care Cleaning and Disinfecting Solution is indicated for use in simultaneous cleaning, daily protein removal, disinfecting, and storing of soft (hydrophilic) contact lenses (including silicone hydrogel lenses) as recommended by your eye care practitioner.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: or over-the-counter: 



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K031521